PHP38
DRUG PRICING REFORM IN CHINA - IMPACT OF THE REFORM FROM A SOCIETAL PERPSECTIVE
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OBJECTIVES: Chinese drug pricing reform initiated on 1stJune 2015 aims to create incentives for efficient management of drug reimbursement budget. This study aimed to assess the potential impact of the reform from the societal perspective. **METHODS:** We conducted a thorough research on the drug pricing reform using three Chinese databases (CNKI, Wanfang, Weipu), Chinese health authorities' websites, relevant press releases, pharmaceutical blogs and discussion forums. This research was complemented with targeted interviews with Chinese key opinion leaders representing authorities' and prescribers' perspectives. **RESULTS:** The reform may include introduction of internal reference pricing (IRP) for drugs with the same active ingredient and dosage form. Therapeutic interchangeability of drugs is an important issue in China. Interviewed opinion leaders consistently agree that there are discrepancies in terms of quality between imported drugs and some locally produced generics. Introduction of IRP may promote the use of cheaper generics with questionable quality. Increased use of low-quality drugs may affect patients' safety and treatment outcomes, and in turn lead to undesired increase of expenditures in other healthcare sectors. It could also increase inequity between different income groups if, as a result of increased co-payment, only the wealthiest could afford high-quality drugs. Additionally, the reform should not be implemented in isolation. Creating effective incentives for cost-containment without affecting healthcare quality requires global, rather than 'micro-level' focus. With hospitals being the main distributor of outpatient drugs in China and economically depending on profit generated from drugs sales, pricing reform should be comprehensive and address restructuring of hospitals' financing and management system. **CONCLUSIONS:** Before introducing the reform on a big scale, all local specificities and challenges should be properly addressed, e.g. the issue of poor-quality drugs. International reference pricing policies cannot be transferred to China without being adjusted for local context. To be successful, the reform requires a comprehensive approach.

PHP39
DRUG PRICING REFORM IN CHINA - AN ANALYSIS OF PILOTED PRICING APPROACHES IN THE CONTEXT OF INTERNATIONAL EXPERIENCE
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OBJECTIVES: Since 2009, the Chinese government has launched a global healthcare reform program aiming to control healthcare expenditure and increase the quality of care. As a part of this program, a new drug pricing reform was initiated starting 1stJune 2015. The objective of this study is to describe the changing landscape of drug pricing policy in China. **METHODS:** We conducted a thorough research on drug pricing reform using three Chinese databases (CNKI, Wanfang, Weipu), Chinese health authorities' websites, relevant press releases, pharmaceutical blogs and discussion forums. The secondary research was complemented with targeted interviews with Chinese key opinion leaders representing authorities' and prescribers' perspectives. **RESULTS:** With the current reform, the government attempts to replace its direct control over prices of reimbursable drugs by an indirect influence. Government pricing and government guided pricing are abolished for most drugs giving manufacturers more freedom to set market prices. However, an introduction of a form of internal reference pricing (IRP), named "reimbursement standard" has been announced. To inform the best approach for implementation of this reform, China is currently running pilot projects in several cities. Sanming is piloting a form of IRP for drugs with the same active ingredient and dosage form; it set the reference price at the price of the cheapest generic. Shaoxing and Anhui are testing the concept of "2nd price negotiation" allowing hospitals to directly negotiate discounts with manufacturers using provincial government procurement prices as reimbursement caps. First results of Sanming and Shaoxing pilots have already been reported, proving their potential for drug budget saving. **CONCLUSIONS:** Many elements of the reform remain unclear and will likely depend on pilot projects outcomes. It seems that the Chinese government is considering adaptation of IRP policies commonly used by European countries. However, foreign pricing policies cannot be transferred to China without being adjusted for local characteristics.

PHP40
CURRENT PROCESS AND FUTURE PATH FOR HEALTH ECONOMIC ASSESSMENT OF PHARMACEUTICALS IN FRANCE
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OBJECTIVES: The Economic and Public Health Assessment Committee (CEESP) was introduced in 2012 as a specialised committee affiliated with the 'Haute Autorité de Santé' (HAS) in charge of providing health economic opinions. This research provides a forward-looking analysis of health economic assessment of pharmaceuticals in France and its impact on market access of drugs. It also provides likely directions of the future French HTA organisation and processes. **METHODS:** We conducted a grey literature search on the HAS website and decision makers' public presentations and comments. This search was complemented with a meeting with experts in market access and health economics, HTA and public health to discuss the current functioning and the likely future path of health economic assessment in France. The main issues that emerged from the search and the discussion were consolidated and analysed. **RESULTS:** Major sources of inefficiencies appeared following the introduction of health economic assessment: (1) Duplication of work between the CEESP and the CT; (2) Resolution of divergent opinions between the CEEPS and the CEPS; (3) Confusion and conflicting information with respect to the current regulation and practices; (4) Lack of an ICER threshold. The likely future of health economic assessment of drugs in France will imply the expansion of health economic assessment scope, the implementation of an impactful ICER threshold, the generalisability of coverage with evidence, and eventually the possible merge of the CEESP and the CT. **CONCLUSIONS:** Major steps in French HTA are expected to occur in the near future. Empowerment of the CEESP (merged or not with the CT) is expected, and it may become the unique or leading committee addressing the HTA of pharmaceuticals in France. However, it is likely that the robust and well-established methodology developed by the CT (SMR, ASMR) to assess comparative efficacy or effectiveness will remain in force.

PHP41
ARE THE IRISH SLOWER THAN THEY THINK? A SYSTEMATIC ANALYSIS OF ALL RECENT NCPE APPRAISALS
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OBJECTIVES: The National Centre for Pharmacoeconomics (NCPE) reviews the cost effectiveness of new medicines following an application for reimbursement in Ireland. All medicines are subjected to a preliminary rapid review (RR, stated to take ~2 weeks) with only high cost products and those with significant budget impact subjected to formal pharmacoeconomic assessments (PEA, stated to be completed in <3 months). This research aims to review all recent NCPE appraisals to determine what proportion of drugs require a full appraisal, the review times and rates of approvals. **METHODS:** Publically available decision summaries from the NCPE were identified (from 1st January 2013 to 31st May 2015) and the outcome, date, indication, and whether a full PEA was needed were extracted. **RESULTS:** 110 appraisals were identified with 43% (47/110) approved following RR. Of these, only 21% (10/47) were reviewed within <2 weeks; the rest taking on average >2x longer than stated (29 days). Of the 57% (63/111) appraisals deemed to require a full PEA, 62% (39/63) were initiated, on average, >5 months post-RR. Only 33% (13/39) of full PEAs were eventually recommended, adding another 5 months (average 152 days) to the process. 27% (30/110) appraisals were for oncology medicines; 90% (27/30) of which required a full PEA. Only 15 were NCPE-appraised, almost all of which were not recommended (87%, 13/15). **CONCLUSIONS:** The total average length of time between start of the RR to final PEA recommendation is up to a year (12 months), which is substantially longer than what is claimed. If companies can convince the NCPE that their medicine is not high cost, nor has a significant budget impact, the RR process can enable rapid reimbursement within 1-2 months. However, if a full PEA is required, this significantly delays reimbursement decisions, with positive recommendations being difficult to achieve, especially for oncology medicines.

PHP42
COULD GIVING COST-UTILITY HTA BODIES NEGOTIATING POWERS HELP BRIDGE THE GAP BETWEEN COST-CONTAINMENT AND BROADENING COVERAGE? A SYSTEMATIC REVIEW OF ALL SWEDISH NLT APPRAISALS OF HOSPITAL PHARMACEUTICALS
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OBJECTIVES: The Swedish Dental and Pharmaceutical Benefits Agency (TLV) make recommendations on whether outpatient prescription drugs should be publically reimbursed with cost-effectiveness being a key criterion. By contrast, no national economic assessment was traditionally implemented for hospital pharmaceuticals, which were typically individually appraised by each county council. However, since January 2011, a national co-ordinating group of Swedish county councils (NLT) can request that selected in-patient therapies undergo a health economic assessment by the TLV, on which the NLT can conduct price negotiations and issue a national recommendation. This research aims to evaluate which drugs the NLT have been appraising and what the final outcomes were. **METHODS:** A systematic search for all publically available NLT recommendation documents up to 1stMay 2015 was undertaken and the drug, date, indication and recommendation, was extracted. **RESULTS:** 50 appraisal documents were identified, 54% (27/50) of which were recommended, 16% (8/50) received restricted recommendations, 16% (8/50) rejected and 14% (7/50) classified as other (deferred/unclear). However, it is important to note that many of the drugs that were approved were not recommended at list price with 41% (11/27) of recommendations being conditional on or following a discount (including confidential discounts) and 11% (3/27) being based on an agreed risk sharing agreement. 2 appraisals were for ZOSTAVAX in shingles, which was previously reimbursed but, based on more recent data, was now deemed to no longer offer benefits that justified its costs. 44% (22/50) appraisals were for oncology drugs only 1 (2%) of which was rejected (YERVOY, but was accepted upon resubmission). **CONCLUSIONS:** The NLT appears to have successfully implemented a process where significant price pressure is exerted on companies with discounts being frequently secured without being too restrictive over coverage. Could giving other cost-utility HTA bodies negotiating powers help bridge the gap between cost-containment and broadening coverage?

PHP43
CLOSING THE GAP BETWEEN HTA AND INNOVATION UPTAKE IN FINNISH HOSPITALS
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OBJECTIVES: Health technology assessment (HTA) is not deeply rooted in Finnish hospitals despite of long lasting attempts to introduce it into routine decision making. Both the processes and content of the HTA approach have been challenged. The EU-funded AdHopHTA project has provided good practices and new tools for hospital based HTA. The aim of this study is to smoothen the introduction of these new tools by examining the obstacles HTA currently faces in hospitals. **METHODS:** Semi-structured group interviews in five public hospitals and two health care centres. Interviewees were clinical unit managers, division managers, and financial or procurement managers. Questions were related to the process of proposing,

evaluating, deciding and procuring new technologies. A mini-HTA sheet was tested during the interview and questions asked about the relevance and clarity of the questions. **RESULTS:** The current processes of the uptake of technologies is relatively similar in all studied hospitals. There are no standard, transparent evidence requirements, nor systems to assess and document the rationales for uptake. The clinicians report their needs in free format; the HTA-tools are not know nor used. After reducing the number of questions in the mini-HTA-sheet and making some changes to its content, order and terminology, the willingness to use increased. Information needed for budget impact analysis was considered of particular interest. Procurement officials were strong proponents of systematic and transparent assessment. **CONCLUSIONS:** HTA tools need to be tailored to the hospitals. Instead of top-down requests for HTA, a low threshold tool is needed to document and justify the need of a new technology. This would pave the way for managers with financial responsibility to request more thorough assessments. This is the point where the new AdHopHTA tools could come in place.

PHP44

REIMBURSEMENT OF TELEMEDICINE IN GERMANY: QUO VADIS - ANYTHING BEYOND SELECTIVE CONTRACTS?

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OBJECTIVES: Telemedicine has been an innovation driver within e-health initiatives in health care in recent years. However, the uptake of such initiatives in Germany is low. Key question on that is if non-adequate reimbursement/funding might be the key reason for the slow introduction of e-health. **METHODS:** We have reviewed German e-health initiatives and assessed the requirements for available reimbursement pathways specifically for telemedicine initiatives in Germany and grouped them according to the application setting. **RESULTS:** Overall there are currently 289 e-health initiatives implemented in Germany in only few centers (mainly Berlin, Bad Oeynhausen, Munich, Hamburg). Telemedicine is being handled as medical devices in Germany within the market access pathway. The exact process depends if the device is an inpatient or outpatient product. In the inpatient setting relevant DRG and OPS codes are applicable; theoretically NUB and additional fee (Zusatzentgelt) could also be applied for. In the outpatient setting, the reimbursement of e-health devices is driven through the respective catalogue of aids and appliances whereas the actual physician service would need to be reimbursed through the EBM (Einheitlicher Bewertungsmassstab). Currently there is no specific EBM code available, and health politicians have missed a deadline in 2014 to create one. Besides the self-payment option as individual physicians services (IGeL) there is the opportunity through selective contracts, particularly Disease Management Programs (DMPs) or integrated care contracts. Most telemedicine projects are currently being covered and tested in the latter ones (e.g. telemonitoring CHF, video Parkinson therapy). An alternative new route could also be the experimental coverage by the joint federal committee. **CONCLUSIONS:** Currently the most relevant market access pathway for telemedicine initiatives in Germany is through selective contracts. Once health politicians put e-health as a priority the introduction of specific DRG and EBM codes could initiate fast adaption and more telemedine introductions in Germany.

PHP45

THE BRITISH ISLES HTA LEAGUE TABLE 2014

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OBJECTIVES: The British Isles comprise 4 countries, each with their own distinct Health Technology Assessment (HTA) body: National Institute of Health and Care Excellence (NICE) in England, National Centre for Pharmacoeconomics (NCPE) in Ireland, Scottish Medicines Consortium (SMC) in Scotland and All Wales Medicines Strategy Group (AWMSG) in Wales. Although all four bodies are obligate cost-utility HTA agencies, they do utilise distinct assessment processes. This research aims to compare the number and type of appraisals and recommendation rates between these bodies during 2014. **METHODS:** All publically available NICE Single Technology Appraisal, SMC, NCPE and AWMSG HTA reports were identified in 2014 and the drug, indication and outcome extracted. **RESULTS:** NCPE conducted the greatest number of appraisals (60) followed by the SMC (52), NICE (29) and the AWMSG (25). However, it should be noted that 68% of NCPE appraisals were through its rapid review pathway (not needing a full pharmaco-economic assessment). The highest rate of positive full recommendations was made by NICE (86%), followed by AWMSG (84%), SMC (79%), and the NCPE (39%). However, there was variation in what proportions of these recommendations were for a restricted sub-population: SMC (47%), AWMSG (29%), NICE (15%) and NCPE (5%). The proportion of oncology drugs appraised was highest by NICE (37%) followed by NCPE (37%), SMC (21%) and AWMSG (4%). **CONCLUSIONS:** The NCPE reviewed the greatest number of medicines but also had by far the highest rejection rates. Although NICE, AWMSG, and SMC had similar acceptance rates, the SMC displayed a greater propensity to restrict indications, and AWMSG (and to a lesser extent the SMC) reviewed a low number of oncology drugs, typically high cost agents that have greater difficulties in attaining positive reimbursement decisions. Thus it appears that in 2014 NICE appeared to be the most generous HTA body in awarding positive recommendations!

PHP46

AN EVALUATION OF A NEW REGIONAL DECISION MAKING PROCESS IN SWEDEN FOR HIGH-COST HOSPITAL THERAPIES

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OBJECTIVES: The decision to fund an in-patient drug is currently made on a regional level by formulary committees in each of the 21 Swedish county councils. A pilot project for a centralised route of assessment for expensive, new in-patient treatments was replaced by a permanent body, Nya Terapier Rådet (NT-rådet), for centralised evaluation in January 2015. The objective of this research is to understand this new process and identify any implications for manufacturers. **METHODS:** Relevant county council and agency websites were used to gather insight into the new NT-rådet evaluation process. A non-systematic literature review was conducted to identify information illustrating potential implications of this new process. **RESULTS:** NT-rådet selects in-patient drugs for centralised evaluation and specifies the degree to which treatment introduction will be centralised. For high priority treatments, Tandvårds- och Läkemedelförmånsverket (TLV), will perform a health economic evaluation, upon which NT-rådet will base their recommendation, which will be accompanied by a monitoring protocol to ensure the organised introduction of treatments to all county councils. For low priority treatments, only a health economic evaluation and recommendation will be issued. Any other treatments will go through decentralised reimbursement processes. NT-rådet plan to publish recommendations on approximately 25 products or important indications per year. To date, NT-rådet has issued eight recommendations, including one joint recommendation for the use of six Hepatitis C therapies. This particular recommendation followed a first of its kind risk-sharing agreement between all 21 county councils and industry, which was a key product of this new process. **CONCLUSIONS:** The new assessment process has centralised the evaluation of some in-patient drugs, but not all. Most new treatments will still undergo the decentralised process. Due to its infancy, the impact of the NT-rådet process on the uptake of new expensive drugs remains to be confirmed.

PHP47

A COMPARISON OF TIME TO LAUNCH AND REIMBURSEMENT FOR NEW MEDICINES ACROSS DEVELOPED COUNTRIES

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OBJECTIVES: To understand the differences in time to launch between countries and the differences in time to reimbursement from launch **METHODS:** We compared time to launch as well as the time to reimbursement from launch of new molecular entities granted marketing authorization between 2009 and 2013 across 18 developed countries. In addition, we conducted a sub-analysis comparing these measures for oncology and first-in-class medicines. A comprehensive analysis of the regulatory and market access landscapes was also assessed in order to understand the reasons behind any differences. **RESULTS:** A large variation in time to launch of all new molecular entities (90 to 430 days) and time to reimbursement from launch was observed across studied countries (90 to 540 days). However, countries could be classified into three distinct groups: Countries with faster time to launch as well as faster time to reimbursement from launch - tended to have regulations mandating quick access, especially immediate coverage through public reimbursement after regulatory approval (e.g. Germany, Japan). Countries with faster time to launch, but slower time to reimbursement - had large private insurance markets but delayed public reimbursement negotiations (e.g. Canada). Countries with slower time to launch but fast reimbursement after launch - had almost exclusively public reimbursement but lengthy public reimbursement negotiations (e.g. France and Italy). Among the slower to launch countries, both first-in-class and oncology products achieved faster times to launch than the average across all new medicines. There was no difference observed in the fast launch countries. **CONCLUSIONS:** Time to launch and time to reimbursement from launch in a country is highly dependent on local market structure and market access regulations.

PHP48

FDA BREAKTHROUGH STATUS VERSUS ACCELERATED APPROVAL – WHAT'S THE DIFFERENCE?

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OBJECTIVES: Since 2013, Food and Drugs Administration (FDA) Breakthrough Therapy status has enabled expedited development and review of therapies where preliminary evidence suggests substantial clinical improvements for serious/life-threatening conditions. However, there was a pre-existing FDA expedited pathway: Accelerated Approval enabling market entry of drugs for serious conditions based on a surrogate endpoint likely to predict clinical benefit with confirmatory trials completed post-approval. This abstract aims to compare access of therapies under both pathways to determine in which distinct circumstances they are being used **METHODS:** All FDA approvals from January 2013-March 2015 were screened for any approvals under Breakthrough Status and/or Accelerated Approval and the disease areas and supportive data packages were extracted. **RESULTS:** Since November 2013, when the first therapy was approved under Breakthrough status, 13 drugs have been FDA-approved under Accelerated Approval and 21 under Breakthrough Status including 8 supported by both expedited programs. For the 14 approvals under Breakthrough Status alone, 11 (79%) were supported by Phase 3 data with the remaining 3 (21%) supported by Phase 2. Of the 6 drugs under Accelerated Approval alone, 2 (33%) were approved on Phase 3 data with the remaining 4 (66%) supported by Phase 2. Of the 7 approved under both programs, only 1 (14%) was supported by Phase 3 data, 4 (57%) by Phase 2 data and 2 (29%) by only Phase 1 data. 86% (12/14) Breakthrough Status alone approvals were for non-oncology drugs versus just 16% (1/6) for Accelerated Approval alone and 0% (0/7) for under both programs. **CONCLUSIONS:** Whereas Accelerated Approval is typically used for oncology drugs, Breakthrough Status has been frequently applied to non-oncology medicines. Accelerated Approval also frequently enables expedited access without available supporting Phase 3 data, unlike Breakthrough Status. Products with supported by both programs have gained access supported by only Phase 1 data.

PHP49

ANALYSIS OF THE REPORTS OF THE NATIONAL COMMITTEE FOR TECHNOLOGY INCORPORATION (CONITEC) IN THE BRAZILIAN PUBLIC HEALTH SYSTEM (SUS), 2012-2015

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